K023725

FEB 0 3 2003

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: Mansour Consulting LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
3-Phone: (678) 908- 8180
4-Fax: (425) 795- 9341
5-Contact Person: Jay Mansour
6-Date summary prepared: November 1st, 2002
7-Device Trade or Proprietary Name: HEMORRHAGE OCCLUDER PIN (HOP)
8-Device Common or usual name: Implantable Staple
9-Device Classification Name: Staple, Implantable
10-Substantial Equivalency is claimed against the following device:

- Hemorrhage Occludor from Surgeon Surgical Instrumentation, Inc. 510k # K890447

11-Description of the Device:

HEMORRHAGE OCCLUDER PIN (HOP) is of 7mm length and 8mm pinhead. It is made out of medical grade Titanium suitable for implantation.

12-Intended use of the device:

This device is indicated to be used to stop massive presacral hemorrhage during surgery.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 3 2003

Marina Medical Instruments, Inc.
c/o Jay Mansour
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, Georgia 30022

Re: K023725
Trade Name: Hemorrhage Occluder Pin (HOP)
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: II
Product Code: GDW
Dated: November 1, 2002
Received: November 6, 2002

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023725

Device Name: HEMORRHAGE OCCLUDER PIN

Indications For Use:

THE HEMORRHAGE OCCLUDER PIN IS INDICATED TO BE USED TO STOP MASSIVE PRESACRAL HEMORRHAGE DURING SURGERY

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PA NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(Division Sign-Off) K023725

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Forma